



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,132	10/29/2001	Donald E. Bobo JR.	CVG-5637	2468

7590 06/30/2006
Debra D. Condino
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, CA 92614

EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
----------	--------------

3735

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,132

Applicant(s)

BOBO, DONALD E.

Examiner

david shay

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 30, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant argues, with respect to the new matter rejection, that the language in paragraph [152] provides support for the amendatory language. While this passage does provide support for sealing the opening in the septum and creating a channel in the surface of the heart chamber, the examiner must note, however, that this cited passage makes no mention of “supportively engaging the medicament delivery catheter with the atrial septum” as claimed in claim 36. Thus the rejection under 35 USC 112, first paragraph has been maintained.

The indefiniteness rejections have been rendered moot.

Applicant argues that Flaherty et al does not anticipate the claims to which it has been applied. The examiner must respectfully disagree. See, for example, Figure 6 and column 13, line 19 to column 14, line 26. The balloon of Flaherty et al clearly performs a sealing function, as it pushes against the tissue to distend it. Thus it is unclear how applicant can assert that the balloon does not seal the tissue when pressure is applied thereto by the balloon. The mere fact that medicament can leak out slowly does not prevent the balloon from maintaining pressure.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed September 2, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “supportively engaging the medicament delivery catheter with the atrial septum at the opening ...”

Claim 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent on “supportively engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening...”

Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36 “the right atrium” and “the chamber of the heart” both lack positive antecedent basis. In claim 45 “the circulatory system”; “the right atrium”; “the atrial septum”; “the opening”; “the chamber”; “the heart”; and “the deployable tissue stabilizer” all lack positive antecedent basis.

Claims 42-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Flaherty et al.

Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, Cox et al, and Kalloo et al. Flaherty et al teach a method of myocardial drug delivery. Jenkins et al teach a method of crossing the septum as claimed (column 1, line 20 to column 2, line 54). Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a bleeding heart. Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to, in order to access the myocardium transvenously, to employ the method of Jenkins et al, since Flaherty et al teach no details of the transvenous placement method; and in order to wedge the probes as in the

method of Jenkins et al, to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al, thus producing a device and method such as claimed.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523). The teachings of Flaherty et al and Jenkins et al and the motivations for combination thereof are substantially as set forth above. Mueller ('523) teach sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue. It would have been obvious to the artisan of ordinary skill to employ the combined drug injection of method of Flaherty et al and Jenkins et al in the method of Mueller ('523) since this is desirable to help maintain the channels, as taught by Flaherty et al, thus producing a method such as claimed.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523) as applied to claims 39 and 40 above, and further in view of Jeevanandam et al. Jeevanandam et al teach the use of multiple vacuum ports to secure a channel-forming device to the cardiac wall so as to form chambers therein. It would have been obvious to the artisan of ordinary skill to provide multiple ports, as taught by Jeevanandam et al, since this provides secure fixation and to provide four ports, since the number of ports can be varied as desired, as taught by Jeevanandam et al, thus producing a method such as claimed.

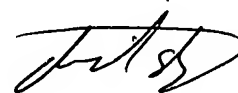
Applicant's arguments filed March 30, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 36-41 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330